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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,397	04/08/2004	Jerome B. Zeldis	CELG-0422	8455

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EXAMINER	
SUTTON, DARRYL C	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
03/21/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/820,397	ZELDIS ET AL.	
	Examiner	Art Unit	
	DARRYL C. SUTTON	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *47-78* is/are pending in the application.

4a) Of the above claim(s) *50 and 56-73* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *47-49, 51-55, 74-78* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's election of species, (a) pulsatile dosage form, (b) nonsolid tumor, (c) chemotherapy and (d) decreased cognitive function, along with claims 47-49, 51-55, and 74-78 in the reply filed on 1/17/2008 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claims 50 and 56-73 have been withdrawn as not being drawn to the elected species.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims rejected under 35 U.S.C. 102(e) as being anticipated by Midha et al. (U.S. Patent 6,217,904).

The claims 47-49 and 52-55 are drawn to a method of alleviating cognitive side effects of cancer or of a cancer treatment.

Midha et al. teaches a pharmaceutical dosage form for pulsatile delivery of d-threo methylphenidate; and that the dosage form of capsules or tablets is administered orally for mood elevation of cancer patients (Abstract, column 10, lines 57-67, column 11, lines 1-4). Midha et al. teaches that salts of the active agents can be used in the dosage forms (column 10, lines 24-46). Midha et al. teaches that "carrier' refers to any component of the dosages forms other than active agents (column 5, lines 5-11, columns 11 and 12, Example 1). Nonsolid or solid tumors are a symptom of cancer, i.e malignant tumor (see Cancer, WebMD).

The prior art anticipates the instant invention insofar as it discloses a method of treatment alleviating a cognitive effect of cancer, i.e. for mood elevation, comprised of administering a pulsatile release tablet or capsule of d-threo methylphenidate or salt thereof.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 47-49, 51-55 and 74-78 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meyers et al. (J. Clinical Oncol., 1998).

The claims are drawn to a method of alleviating cognitive side effects of cancer or of a cancer treatment.

Meyers et al. teaches that patients with malignant glioma develop progressive neurobehavioral deficits over the course of their illness, caused by both effects of the illness and the effects of radiation and chemotherapy (page 2522, 1st column, "Purpose", 1st column, 2nd paragraph, 2nd column, 2nd paragraph). The effects of the treatment and the pattern of deficits are consistent with those seen in AIDS dementia complex (page 2522, 2nd column, 2nd paragraph). Methylphenidate has been used to treat cognitive deficits and depression of patients with AIDS (page 2523, 1st column, 4th paragraph), and has been shown to alleviate the delayed effects of chemotherapeutic treatment of pediatric brain tumor and leukemia patients (page 2523, 1st column, 1st paragraph, page 2526, column 1, reference 18). Methylphenidate hydrochloride is a

mixed dopaminergic-nordrenegrgic antagonist with pharmacological properties similar to those of amphetamines (page 2523, Patients with primary malignant gliomas that had chemotherapy treatment were tested for assessed for cognitive function deficits caused by tumors and treatment; the patients were given 5 mg of methylphenidate twice a day (page 2523, column 2, "Table 1", page 2524, 1st column, "Neuropsychologic Test Battery", "Treatment Plan"). Significant improvements in cognitive function led to methylphenidate being suggested as an adjuvant therapy for brain tumor patients (page 2524, 1st column, "Discussion", page 2526, 2nd column, 1st paragraph). It is known in the art that methylphenidate is used in therapy as a racemic mixture of d and l-threo enantiomers and that the l-threo methylphenidate isomer makes no contribution to therapeutic efficacy and is associated with undesirable side affects (see Mehta et al., U.S. 5,937,284 and Midha et al., U.S. 6,217,904). Pulsatile release dosages of d-threo methylphenidate hydrochloride in the form of capsules and tablets are also known in the art (see, Mehta et al.).

Meyers et al. does not teach the use of a pulsatile release dosage form of a tablet or capsule. Meyers et al. does not teach administration of d-threo methylphenidate or a pharmaceutically acceptable salt thereof.

At the time of the invention, it would have been obvious to one of ordinary skill in the art to modify the method of Meyers et al. to include a pulsatile release dosage of d-threo methylphenidate hydrochloride, since the l-threo methylphenidate is associated with undesirable side affects and since patients were given two doses per day, a pulsatile release dosage form would eliminate the need to and the time required to

administer two separate doses to the patients. It would have also have been obvious to modify the dosage form to that of a tablet or capsule because they are standard dosage forms in the pharmaceutical art for pulsatile release dosages.

All claims are rejected.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl C. Sutton whose telephone number is (571)270-3286. The examiner can normally be reached on M-Th from 7:30AM-5:00PM EST and on Fr from 7:30AM-4:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached at (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Darryl C Sutton/

Examiner, Art Unit 1612

/Frederick Krass/
Supervisory Patent Examiner, Art Unit 1612